Performance-Based Methods

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Performance Based Methods have been around for a long time. It could be argued that ALL methods were performance based before the lawyers, regulators and managers got their bureaucratic little hands on them! If these methods have been around for so long why is there a debate? Well, I think that the debate is pretty well over and what we are in fact involved with is the problem of how PBM's should be used. There is a lot of fogginess shrouding this subject. I hope to shine some light on the subject by posing, discussing and perhaps, with your help, even answering some of these questions.

PBM's...
What are they? What do they look like? What are the benefits? What are the liabilities? What are some issues and approaches? Who might use them? Where Do We Go From Here?

What Are Performance-Based Methods?

Well, the quick answer is; I'm not sure! Different people, from different groups seem to have different opinions. In most cases, close inspection reveals that the differences are more apparent than substantive.

In general terms, Performance Based Methods define *what* is to be accomplished rather than *how* the objective will be achieved. Some proposed definitions are:

1) a method that produces data that meets specifications (and does not rely upon a prescription to achieve this goal);
2) a monitoring approach that permits the use of appropriate analytical methods that meet established, demonstrated method performance standards, based on agency (customer) data quality (objectives) needs. Minimum required elements of performance such as precision, accuracy, sensitivity, specificity and detection (criterion) limits must be specified and an available method must be shown to meet the method performance standards;
3) An analytical procedure containing the necessary method performance specifications to assure the desired quality of performance;
4) An analytical method containing the necessary method performance specifications to assure the desired quality of performance.

One function of any definition is to enable the differentiation of the defined entity from all other entities. None of these definitions is particularly good at separating prescription methods from PBM's. Many proponents of prescription methods would proclaim that their methods contain the necessary performance specifications and thus fall within the definition.

What is the purpose for the definition? To provide more flexibility in the choice of analytical methods. In order to do this we must have a system that provides some assurance that all permissible choices meet agreed upon standards and that these standards exist for all relevant criteria.

There are two main instances where an opportunity to be flexible is encountered, changing an old method and selecting a new one. Prescription methods, of course, do not allow either. The PBM system must provide criteria and standards that can assist in the determination of whether a change has been made to an old method or whether a new method has been adopted or created. The system must also assist in the selection of new methods.

Another opportunity for flexibility can be created by separating the sample preparation stage from the analyte determination stage. PBM systems must be able to deal with this modularization of the analytical system. Other subsystems which are often modularized are the sampling, aliquoting and data reporting operations.

Following this path of reasoning leads us to a **provisional definition** of a Performance Based Method:

"A method that is part of a quality management system and is primarily based on a strict definition of the outcome of it's application and which contains criteria and standards for the creation of guidelines for how the outcome will be achieved".

The idea of a PMB as part of a larger system is critical to this definition and is one of the attributes of the method that differentiates it from a prescription method. As part of a quality management system the PMB lives in relation to other parts of the system like;

- Data Quality Objectives which determine the *'strict definition of the outcome'* of the PBM;
- Quality of Design* and sound analytical principals which determine what the *'guidelines for **how** the outcome will be achieved'*;
- QC module;
- QA module;
- Data Reporting module;
- Quality of Design Loop^ ;
- Method, Laboratory and Technologist Accreditation
- Traceability
- etc.

This brings us to the subject of the model or format for such a method.

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* When a method undergoes significant modification or is first created the Q of D documentation can be quite lengthy and is probably best kept as a separate but permanently linked file.

^ This loop forms the basis for Continuous Quality Improvement. The QC data is rolled up into QA documentation as the method is applied. Periodically, the issues highlighted by the QA system are addressed by a method review and update. This may, for example, result in the identification of new sources of determinate error and thus new QC procedures. These constitute a method change and must be documented in the Q of D file.

What Do Performance Based Methods Look Like?

Well, based on the above they should look **flexible and modular**. More than this, since the Performance Based Method approach is really a system, of which the method is only one component, PBM's must have **ways and means of interfacing** with the other modules in the system. There are a number of proposals for the format of performance based methods. None seem to have received general approval. The following model introduces a suggestion for a PMB format.

An outline of what a PBM may look like is:

INTRODUCTION

The introduction could describe the reason for the method, the expected use of the data and the limitations of the method.

General Sample Information:

There are usually three groups that are interested in sample information 1) the sampler, 2) the analyst and 3) the data user. In some situations it may be helpful to further define a) field information that is important for data interpretation and b) information that is of primary importance to laboratory staff i.e. information related to safety or the presence of possible sources of determinate error. This level of categorization should help with administration and management of the PBM.

The following table lists a some examples of these information elements (information flows from left to right):

Sampler		Analyst		Data User	
Field	Lab	Field	Lab	Field	Lab
safety	homogeneity	aliquot	safety	geographical	data qualifiers
shipping	phase info	etc.	method attributes	regulatory	data base
container	preservatives		QC	admin codes	report format
custody	date sampled		QA	comments	dates
sample size	replicates		analyst info	etc.	comments
protocol	notes		storage&retrieval		etc.
etc.	etc.		comments		
			etc.		

These are just a few of the information items that may be necessary to specify in a PBM. By adopting this, or some other, categorization scheme the PBM can be more easily managed. For example, if the PBM is to be employed in a compliance monitoring situation where a continuous feedback process control model is adopted there will be little or no sampler functions. The PBM is simply formatted without the checklist items under 'Sampler'.

Note that these items constitute the criteria that a PBM would require but that each of these must be defined by associating them with standards, procedures and documentation / audit protocols. These criteria and standards form part of the guidelines for ***how the outcome will be achieved.***

Range of Data Quality Objectives Serviced

Data Quality Objectives are associated with a project or with a particular clients sample(s). It is these objectives that provide the PBM with a *'strict definition of the* ***outcome*** *of it's application'*. Since a PBM must satisfy a number of DQO's and since these are not, in the general case, known prior to the development or modification of the method it will be necessary to specify within the PBM a range of DQO's for which the method is expected or has demonstrated capabilities. Moreover, the PBM should indicate the cost/benefit of each of the possible choices which could be selected when adapting the PBM to achieve the required DQO's. Thus, because the purpose of the PBM system is to provide flexibility, an important component of the method is a ***cost/benefit analysis***. This analysis serves as a basis for selecting a specific arrangement of the available alternatives.

Technology Specification

This section should include two analyses, an analysis of error and a cost/benefit analysis.

Allowable technologies e.g. ICP/OES or ICP/MS should be listed along with the sources of determinate error for each of the technologies. Generic QC requirements should be associated with each potential source of error e.g.;

- ICP/OES; Spectral-Overlap, InterElement Correction Factors Must Be Employed and residual indeterminate error must be propagated to final result
- ICP/MS; Molecular Interferences, species must be unambiguously monitored and corrections applied and residual indeterminate error must be propagated to final result
- All Technologies; reagent blank contamination is a potential source of error, carry at least three reagent blanks and apply QC protocol as specified in SOP RB95-DE*

Where applicable, a cost/benefit analysis should be included so that people have a basis for choosing the technology. In analytical chemistry this usually involves a tradeoff between cost on the one hand and speed and accuracy on the other.

END OF INTRODUCTION

A separate section may be necessary for each parameter. Each section could consist of;

Section1:
Parameter
The exact form of the parameter should be defined along with the reporting format. Issues like stability, competing chemistries and interpretation issues should be dealt with.

Calibration Information
a) Range of Valid Calibration
b) Detection Capabilities
c) Low Level Reporting

* As with prescription based methods Standard Operating Procedures are a valuable tool for systematizing and documenting procedures that extend across many methods.

Calibration of the Method

Calibration is the process of establishing the stimulus-response relationship of a well defined optimized analytical system. This is the point in the life of the method when external validation begins. The actual process for achieving this must be documented and subsequent standardization should be evaluated by reference to the calibration. Calibration is usually more exhaustive than standardization because it is a means of establishing both the external validity of the system and the dynamic range of the calibration curve.

Standardization of the Method (Relative Methods)

Standardization is the process of bringing an analytical system back into compliance with the calibration. It is usually less exhaustive than calibration. Some methods are quite accurate using multipoint calibration and only one or two point standardization. Others are calibrated with a series of matrix matched standards but are standardized with a completely different matrix. This is quite valid if it can be proven that there are no sources of error associated with the matrix and the function of the standardization is merely to re-establish the stimulus response relationship with a known and constant stimulus.

In any case a means to relate daily standardization to the initial calibration is necessary and this must be documented. In the many cases, particularly with prescribed methods, the stimulus-response relationship is established using other than calibration quality standards and the method is externally validated by simply exposing it to performance evaluation by samples produced by an external agency. This will be necessary but in many cases not sufficient for PBM's because external validation will assume increased importance as multiple technologies, each with their own sources of determinate error, will be available as choices for the method.

Verification of Performance

This section is similar to what is found in most prescription based methods i.e. statements of expected (based on propagation of error calculations) or demonstrated (based on observed performance) measures of the capability of the method to estimate central tendencies and dispersions (accuracy and precision). Analysis of reference materials, performance evaluation samples, surrogate recovery, spikes, and duplicates all have a role to play here.

These figures are attributes of the method as are detection limits. It is important to deal with detection limits as performance indicators and to think of them as method attributes. They should thus be considered in this section and separate from the section dealing with data reporting and data qualifiers. In the general case they are not attributes of the sample. In the specific case, when it can be proven that all samples are drawn from the same population as those employed to establish the limits, they could be used as data qualifiers but the issue of low level reporting is clouded by the reality of detection Vs quantification.

Specificity and selectivity are also attributes of the method and should be discussed here.

Quality Control Requirements

Quality control requirements should be associated with known sources of error so that the most efficient action can be taken in the event of a failure. The PBM should specify the procedure and clearly identify it as such. The standard(s) for evaluation of the outcome of

the QC test should be clearly stated as should the action(s) to be taken along with the necessary documentation protocols. The procedure should specify which information is to be passed to the QA system and how this is to be accomplished. Laboratory managers may wish to assign responsibilities for these tasks within the PBM.

Quality Assurance Requirements

The data which is passed from the QC system is dealt with here. In addition, things like accreditation, certification of laboratory & analyst skills and proficiency requirements should be summarized.

References

Appendix

Perhaps an example method?
A helpful addition may be a flowchart illustrating the various options for assembling the PBM.

What Are Some of the Benefits of PBM's?

FLEXIBLE ALTERNATIVE: To answer this question it is necessary to know what is wrong with the current approach and this in turn requires one to have a pretty good appreciation for what the 'current approach' is. I suppose that there are many 'current approaches' but for the purposes of this discussion the current approach that serves best as a reference point for PBMs could be labeled the 'recipe' approach. In this model the overriding assumption is 'if a method is sufficiently well developed and clearly written then someone with adequate training and experience will obtain accurate results if they follow the method exactly'. The difficulty is; 1) this sometimes produces results that are not fit for the use intended and, 2) even if it does work the method becomes entrenched and there is little flexibility when new technology is developed.

The introduction of new technology under the 'recipe' approach is difficult. New approaches are generally held for review until sufficient experience was accumulated for a decision to be made. ICP-MS, SFE, and microwave sample decomposition and extraction are some of the technologies which were impeded by this approach.

ASSIGNMENT OF RESPONSIBILITY FOR QUALITY: Commercial laboratories are designed along the manufacturing model. They produce a product called a result. This commodity must be produced in the shortest possible time for the lowest possible cost and they must receive the highest possible price for it. The best way to do this is with a manufacturing process that is well defined, i.e. a prescribed method. Moreover, with the prescriptive method approach the purchaser of this commodity has an interest in paying the laboratory to follow the procedure rather than get an accurate result. This creates less problems for the consumer particularly when the produced result is biased low because it allows an effective defense; "we followed the procedure".

One of the most serious shortcomings of the 'recipe' approach is that some laboratories are producing data that is biased or otherwise compromised. This can happen even when an approved method is followed exactly and the QC is within acceptable limits. This is because the samples may carry a source of determinate error that was not anticipated at

method development time. The laboratory personnel may suspect such bias but with the client can place considerable financial pressure on the laboratory to report the result as less than some regulated value EVEN WHEN IT IS SUSPECTED THAT THE SAMPLE DOES NOT COMPLY. The client has some justification in doing this, rationalizing that they 'followed the method to the letter and it is not their fault if the EPA or the method development agency was too stupid to anticipate all possible sources of determinate error in their samples'. I have been told by lab managers that they have been instructed by their client not to carry out, or at least not to document, any further investigations involving their samples. I suspect that this practice is more wide spread than is generally acknowledged. This verges on illegal, is certainly not in the spirit of the law and is, by most standards, unethical!

The PBM approach places the emphasis for ensuring quality (a.k.a. fitness for purpose) with the people producing the result (samplers, handlers, and analysts) rather than primarily focusing on the method as the vehicle for delivering quality data. The recipe approach tends to push analysts into the role of measurement technologists whereas the PBM approach tends to broaden the responsibilities of the analyst and rely more on the skills of analytical chemistry. This is at once the strength and the weakness of the PBM approach. By empowering the analyst to make decisions about quality during the analytical process we place the decision making and the responsibility in a more effective strategic position. For me, one of the central issues of is this one: do we rely primarily upon the people developing and managing the method, or do we rely upon the analytical technologist? With the PBM approach we can do both.

The benefits of this are:

1) **clients** can use a wider variety of laboratories thus providing competition and flexibility;
2) **lab managers** have more latitude in choice of resources and their management;
3) **technology developers** are less constrained when allocating resources for research;
4) **analytical chemists** are less constrained when developing or modifying methods;
5) the increased emphasis on the **analyst** for the provision of quality data should produce more flexible, qualified and empowered analysts which in turn should produce higher quality data, particularly in cases where the sample carries a source of error that was not adequately controlled in the method.

Summary:

- **quality** is defined in a more effective way;
- analyst and management **flexibility**;
- encourages **method and technique development**;
- more efficient and **better methods & results**;
- more **highly skilled analysts**.

What Are Some of the Liabilities of PBM's?

COST: Many people disagree with the PBM approach. It is certainly more difficult to participate in a system where you are responsible for the outcome and are not simply checked with respect to 'following the steps'. Methods must be developed, chosen and deployed so that a quality result is produced. This means that laboratory managers and analysts must demonstrate competencies that extend well beyond simple implementation and carrying out of prescribed procedures. Analyte, level of concentration, matrix and any other factors that could carry determinate error become of primary concern to these people

because the responsibility is no longer essentially with the agency prescribing the methods. The development of these competencies will cost both time and money. Moreover, the power for implementation of a quality system that involves PBM's resides with lab management. It will cost time and money to develop the expertise and the systems. The solution to this concern may emerge from a realization that not all situations warrant a PBM solution. Prescription based methods will continue to be the most cost effective and probably the most accurate when applied to samples of well characterized and homogenous composition and when the technologies applied are mature and well accepted. PBM's will be necessary and may even be more cost effective when samples are less well characterized or when new technologies are being applied to the problem. Some examples of where one approach may be more suitable over the other are:

Example	Approach
1) homogenous process-stream monitoring	prescription
2) high impact, well defined, complex testing like AIDS etc.	prescription
3) long term programs where trending is more important than absolute accuracy	prescription
4) situations where the result is defined by the method e.g. 'ether extractable oils'	prescription
5) non-homogenous, difficult to characterize sample streams	PBM
6) poorly defined testing, e.g. qualitative screening of dump sites	PBM
7) short term projects where absolute accuracy is required across laboratories, sampling sites, jurisdictions, methods etc.	PBM

CULTURE: When managers implement a quality system that is built around prescribed methods they generally are rewarded by becoming more 'plugged in' to the information. It is easy to believe that the method is a 'constant' the attributes of which can be known. Some will interpret the concept of PBM as being a loosening of standards and re-label their prescriptive methods 'PBM'. This could result in a lowering of the quality of the results from these methods.

COMPLEXITY: Accreditation may become the savior for some. This is a dubious asset because, by itself, accreditation does not guarantee quality. Indeed, accreditation is largely concerned with quality of conformance not quality of design. Accreditation ensures that the procedure has been followed as prescribed but it does little to ensure quality of design. Experience has shown that accreditation can be a wall to hide behind.

ABSENCE OF GUIDELINES, CRITERIA AND STANDARDS: It will be important to devise an agreed upon protocol whereby a new PBM can be demonstrated to be valid and through which it can be characterized i.e. what are the attributes of a PBM? Test method equivalency is probably a necessary but insufficient criteria. When criteria for establishing validity have been agreed upon it will be necessary to formulate standards under each of the criteria or at least to have a guideline for developing such standards.

Summary:

- increased **cost** to develop;
- change in **culture** (usually painful for someone);
- increased **complexity** of implementation and administration;
- **guidelines, criteria and standards** must be developed and agreed upon.

What Are Some of the Issues And Approaches?

Some relevant questions are:

1) who are the stakeholders?
2) what are the guidelines?
   2a) which criteria?
   2b) what standards?
3) who develops them?
4) who assures that they are adhered to?

STAKEHOLDERS: Among the stakeholders are data users (e.g. regulators, lawyers, engineers, biologists), laboratory managers, analytical chemists and technicians, instrument companies and suppliers. There is a wide variety of needs within each of these categories and the guidelines must provide a consistent framework for everyone to take effective action.

GUIDELINES: Guidelines will be required for the various aspects of the PBM system: preparation of DQO's, Specification of Method Performance Criteria, Specification of Method Audit and Proficiency, Specification of Reporting Protocols. In order to achieve the goal of flexibility these guidelines should focus on trapping and correcting error as well as ensuring that the correct information (not just data) is generated and communicated appropriately.

CRITERIA & STANDARDS: Some Suggestions For Analytical Methods

To provide the benefits that we have discussed and to avoid the liabilities PBM systems must have guidelines with criteria and standards that enable their effective use. These should assist in deciding if the PBM approach is best and should also provide a way to ensure the quality of the method a) when developed (Quality of Design) and b) when being chosen and c) when being applied (Quality of Conformance).

WE MUST BE CAREFUL WHAT WE STANDARDIZE: Some groups are proceeding in the right direction but they are still searching for a prescription to achieve their goals rather than guidelines that can be used to define a system. For example, in a document asking for public participation the discussion topics were:
"establishment of standardized QC for analytical methods";
and
"establishment of standardized data elements for reporting analytical results".

The document proceeded to list a set of mandatory QC procedures like spikes, duplicates reagent blanks and others that would be necessary to include in a PBM. This begins to look less like guidelines and more like a prescription. Instead it may be more effective to ask: "What possible sources of determinate error are associated with this PBM"? If reagent blank contamination can never affect results then the inclusion of reagent blanks is a waste of money and time. The focus should be on the sources of error, their control and assurance by setting guidelines for handling error and specifying criteria and standards.

'Standardized QC tests' to demonstrate that a method change, adoption or development has not degraded method performance may not be the best approach because QC, by definition, is directed at problems of *conformance* not at problems of *design*. During the process of method change, adoption, or development the focus should be on Quality of Design and the PBM approach should provide guidelines for assurance of the design process. Once the PBM is in place quality of conformance becomes an issue but from the point of view of the

practitioner the method looks very much like a prescription method. Once QC procedures have been linked to known sources of error (and therefor are associated with action procedures) the 4-step QC process i.e. 1) test, 2) inspect/compare, 3) take action, and 4) document work in much the same manner as with prescription methods. With PBM's it will be even more important than with prescription based methods to periodically feed the QC information into the Quality of Design loop.

METHOD ATTRIBUTES Vs DATA QUALIFIERS: The PBM itself should carry those data reporting specifications imposed by the method attributes e.g. soluble / insoluble, MDL, typical uncertainties*, etc.) and it would carry only those QC procedures that are technique specific (e.g. IEC's in ICP/OES). Data Qualifiers should not be proclaimed in the method but should be determined by the DQO's for the clients who receive data from the method. The PBM should be able to feed data into a reporting subsystem that does not change the data with respect to those attributes imposed by the method but should append data qualifiers that are required by each client. For example, a PBM may produce Cd concentrations in ground water. The core method should determine the MDL (a method attribute) but the low level reporting requirements may be different for different clients. The data is still the same and the MDL is independent of client. However the data qualifiers may be different for different clients and one may want to see a result like 0.034 <MDL(.05) <Provincial Water Quality Criteria (.2) whereas another client may wish to see a result like 0.034 <RDL(.5). The separation of method attributes from data qualifiers allows for clearer criteria and standards for PBM's.

DIFFERENTIATE THE METHOD: For similar reasons it may be wise to separate the sampling, sub-sampling and analysis phases into separate methods. This should make the task of tracing where errors were introduced when a change has resulted in compromised data. Also, the objective of flexibility is achieved by allowing managers and analysts to choose from various preparation methods and stream the samples to a particular measurement method. Measurement methods based on different technologies are in general different methods because the sources of both determinate error and indeterminate error differ. Using similar criteria, preparation methods that carry fundamentally different sources of error require different QC protocols. Therefor they are different. If the analyst can argue and demonstrate that the sources of error for the two techniques, when applied to a specified set of samples, are the same then the difference is a method change not a new method.

CALIBRATION & STANDARDIZATION: Another opportunity for improving PBM's is to clearly separate the calibration process from the standardization process. This would provide assurance that different PBM's are at least externally validated and may result in more effective use of international certified reference materials.

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* an excellent treatment of uncertainties and how they can be used is provided in the document A Guide To The Expression of Uncercainty In Measurement, ISO Geneva 1993.

LINK QUALITY CONTROL TO SOURCES OF DETERMINATE ERROR: PBM's are supposed to allow flexibility while ensuring quality and this quality is, to a large extent, the responsibility of the laboratory staff. The prescription based approach attempts to measure quality into a product by specifying a more or less comprehensive list of quality control procedures which had to be followed. To provide flexibility and cost effectiveness in the PBM approach QC should be linked to sources of determinate error. For example, if experiments performed at method development time have demonstrated that proportional determinate error is the main source of error then QC procedures like taking different aliquot sizes or performing spikes is not only a waste of time and money it is misleading because the analyst would interpret the results as being accurate when in fact some action should have been taken.

PBM's should also be more rigorous with respect to how QC data is dealt with. The four basic steps of QC should be an explicit part of the method i.e. 1) test/measure, 2) compare against expected (usually a Statistical Process Control population parameter), 3) take action (or not), and 4) document. The action will be considerably more effective if the QC procedure is linked to sources of determinate error.

LINK QUALITY ASSURANCE TO A QUALITY OF DESIGN LOOP: The Quality Assurance system (among other things) is the repository of the results of the QC subsystem. The documentation listing or summarizing the QC performance of a PBM should be periodically reviewed and an analytical audit of the method should be performed with a view to making it more efficient and to eliminating or reducing the sources of error that have been identified during the last period. This helps to create a culture of continuous quality improvement which I believe will be crucial to the success of the PBM approach.

DQO's BECOME VERY IMPORTANT: Since PBM's plug into the scheme after the DQO's the PBM approach will need guidelines for the specification of DQO's so that the PBM can be linked with the users needs. If this link is not clear the person(s) responsible for choosing, adopting or developing the method will have little basis for their activities.

DEVELOPMENT OF PERFORMANCE CRITERIA AND INDICATORS: DQO's are a tools for the user to specify the quality of results that are required. Performance criteria are tools for the analytical chemist and laboratory manager to communicate the capability of the process (method) that they are offering. DQO's should live outside the method, PC should live inside the method. They should link in a manner that enables data users and laboratory staff to agree upon the method that will be used to achieve the objectives. The specific Performance Indicators used that would be selected for each of the criteria would depend on the DQO's of the client and the PC's of the method. Some Performance Indicators are: detection, accuracy, precision, specificity, selectivity, and ruggedness with respect to various parameters.

PROFICIENCY MONITORING: Since QC procedures are flexible and are linked to sources of error that are not only technique and method specific but may also be laboratory and personnel specific it will be necessary to validate PBM performance with a proficiency monitoring system. This includes things like method performance evaluation using test samples, skills and competency monitoring for analysts as well as broad method audits to ensure that guidelines and procedures are followed and that data reporting is correct (particularly QA of software used for this purpose).

The above suggestions are by no means a comprehensive list of PBM criteria but they are things to consider when developing guidelines for a PBM based system. Who will develop these guidelines and who will ensure that they are being followed? Well, the quick answer is 'I don't know'. I suspect that it will continue to be a bottom-up process until the concepts are clear enough for extreme positions to be taken. At this point a group or agency may be able to synthesize a PBM system that is generally acceptable or adaptable to the analytical community. Until this happens specific data users and laboratory managers will continue to experiment with the concepts.

Who Might Use PBM's?

The EPA, Office of Solid Waste has been using PBM's for more than 10 years and they are working to promote the philosophy throughout the agency. EPA Office of Science and Technology (within EPA Office of Water) is reviewing ways to increase flexibility of method change in existing '40 CFR Part 136 test methods'. The MOEE MISA program took this approach from the beginning of the program. The USEPA Contract Laboratory Program (CLP) employs the PBM approach when the required work does not have a routine method that could be prescribed.

PBM systems are probably not the best approach in all cases. Prescription methods will continue to be relied upon for analysis when the problem is well defined and mature, cost effective methods exist. The PBM approach will continue to flourish when stakeholders are working with less well defined problems, when new technology is being incorporated, when clear quality of conformance protocols cannot be easily applied and when quality is more dependent upon the experience and judgment of the practitioner than upon strict adherence to a procedure.

Where Do We Go From Here?

There is a qualitative difference between a Performance Based Method and a prescription method. Both work best when viewed as part of a larger overall system but PBM's are critically dependent on this system whereas prescription methods are more independent of the Quality Management system.

The goal is to provide a framework for the development and use of methods that produce quality results in a reasonable time and at the lowest possible cost. The issue is really not which approach is better but which is better in a particular case. I suspect that the so-called 'prescription approach' will continue to be used where it is appropriate and that the PBM approach will continue to grow and be successful in cases where it is most effective.
The debate should continue, not on which approach is better but on defining the PBM approach and developing more powerful conceptual tools to augment it's development. The experience of well implimented PBM systems will determine how rapidly and extensively the approach gains acceptance.

END